EXHIBIT G

Dec 5, 2005, rev. Feb. 2005

Exhibit B
Specifications for the Product

Quality Assurance, Production Controls & Specifications

It is Brassica Protection Products' (BPP) objective to supply the highest quality products to the industries served. All materials produced and sold under license from BPP shall be manufactured in such a way to assure the highest quality standards and shall meet release specifications approved by BPP. Materials and/or products licensed from BPP are referred to as "product(s)" in the following sections.

BPP reserves the right to audit all aspects of the production of its licensed products and shall approve in advance and in writing all product specifications and manufacturing procedures. All manufacturing methods, quality control testing, packaging and labeling, storage, and distribution shall be in substantial compliance with the Federal Food Drug and Cosmetic Act, DSHEA, NLEA and with the cGMP principles set forth 21 CFR, parts 210, 211, and 100 and shall include, but are not limited to, the following:

1. Quality Control:

(a) Each manufacturer of products shall have a quality control unit with responsibility and authority to approve or reject raw materials, components, in-process materials, packaging material, labeling, and finished goods. The quality control unit shall have authority to review production records for procedural compliances and lot-to-lot uniformity. In the event that deviation or rejections occur, the quality unit shall investigate and follow up with corrective and preventative action. The quality control unit shall be responsible for approving or rejecting products manufactured, processed, packed, or consigned to others.

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, packaging materials, in-process materials, and products shall be available to the quality control unit.

(c) The quality control unit shall have the responsibility and authority for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, composition and purity of the product.

(d) Written Standard Operating Procedures (SOPs) shall indicate the responsibilities and procedures of the quality control unit. Adherence to SOPs is

required by BPP. A reasonable document control method shall be employed to preserve the integrity, necessity, and viability of SOPs.
(e) Quality assurance audits of all aspects of product production, testing, storage, and distribution shall be conducted no less frequently than once a year by the quality control unit or qualified outside contractor.

2. Production Facilities:

(a) Any building or buildings used in the manufacture, processing, packing, or holding of a licensed product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

(b) Any such building shall have adequate space and systems for the orderly placement of equipment and materials to prevent mixups between different components, product containers, labeling, in-process materials, or products, and to prevent contamination. The flow of components, product containers, labeling, in-process materials, and products through the building or buildings shall be designed to prevent contamination or adulteration.

(c) Operations shall be performed in clean, segregated, vermin-free, properly ventilated areas of adequate size for the purpose. Routine facility maintenance shall include vector control and abatement.

3. Production Process:

(a) All products shall be produced by uniform, written master manufacturing directions (or procedures) to ensure lot-to-lot uniformity. Production and process controls shall be designed to assure that products have the identity, strength, quality, and purity they purport or are represented to possess. In advance of production, master manufacturing directions shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit. A document control system shall be used to issue, revise, amend, or retire manufacturing procedures.

(b) All products shall be produced by validated manufacturing processes. For the purposes of this requirement, "validated manufacturing process" means data which demonstrate, through actual production of at least three lots, that the written manufacturing directions will repeatedly produce a product which meets specifications and that the critical process control points and quality control testing are sufficient to insure the requisite product quality.

(c) To assure uniformity from lot-to-lot, each production batch or lot shall travel with a lot-specific copy of the manufacturing procedures (known as a batch record). Batch records shall include batch size, start and completion dates for each step, and steps shall be completed sequentially exactly as directed and recorded. Each batch record shall include lists of any and all materials, components, and labels issued to that batch. The batch records shall include summaries of the quality unit tests and criteria for ultimate batch release.

(d) During manufacturing, employees shall sign batch records clearly and by hand to indicate involvement and work completion per directions. At critical control points, one person shall sign for completion and a second shall sign independently, confirming the complete and appropriate action. Deviations during manufacturing may only be undertaken with prior consent of the quality control unit and an appropriate notation in the batch record.

(e) For each lot of product produced, completed manufacturing batch records and distribution records in form comprehensible to BPP shall be maintained for a minimum of 3 years, thereby providing accountability, documentation of procedural compliance, and full lot traceability.

4. Control of Microbiological Contamination:

(a) Appropriate written procedures, designed to prevent objectionable microorganisms in the product, shall be established and followed.

(b) Such procedures shall include validation of any process used to reduce microorganisms in the product.

5. Reprocessing:

(a) Written procedures shall be established and followed prescribing a system for reprocessing (or reworking) batches that do not conform to standards or specifications. The goal of rework shall be to ensure that reprocessed materials conform to established product standards, specifications, and characteristics.

(b) Reprocessing shall not be undertaken without prior review and approval of the quality control unit. Full traceability of reworked product is required.

6. Personnel qualifications:

(a) Each person engaged in the manufacture, processing, packing, or holding of a product shall have education, training, and experience, or any combination thereof, to enable that person to perform assigned functions. Training shall be in the particular operations that the employee performs and also in current good manufacturing practice as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them.

(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a product shall have the education, training, and experience, or the combination thereof, to perform assigned functions in such a manner as to provide assurance that the product has the safety, identity, strength, quality, composition and purity that it purports or is represented to possess.

(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each product.

7. Laboratory Controls & Release Testing:

(a) The establishment of specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be reviewed and approved by the quality control unit. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified. A controlled SOP document system will be used for these purposes.

(b) Laboratory controls shall include the establishment of scientifically-sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, product containers, in-process materials, labeling, and products conform to appropriate standards of identity, minimum strength, quality, and purity. All laboratory procedures, methods, tests, and results shall be in writing and become part of the controlled SOP document system.

(c) The quality control unit shall have the sole responsibility for laboratory controls and release testing as described here. At the end of processing each batch and upon passing all final tests, batches are released. A Certificate of Analysis is issued, bearing the signature of a quality control unit member, to record and communicate the characteristics of the batch relative to standards

and specifications. BPP reserves the right to control the content and format of the Certificate of Analysis template so as to ensure compliance with standards and specifications.

(d) All components, raw materials, and finished products shall be quarantined and tested against written specifications and may only be released for use upon written authorization of the quality control unit following review of testing results. Such test results shall become part of the permanent record for each lot of product produced.

e) A minimum of two samples of all components, raw materials, and finished products shall be set aside and retained for future reference. Identification codes, lot numbers and reference dates shall be indelibly marked on retention samples. Samples shall be of sufficient size to allow for a full battery of tests as those used for material or batch release. Samples shall be stored in an orderly fashion facilitating retrieval. Samples shall be stored in opaque containers with similar moisture vapor barrier and other arrangements as the goods they represent, and they shall be stored for not less than 3 years.

8. Packaging & Labeling:

(a) All labeling must be approved in writing by BPP. Any use of The Johns Hopkins University name or logo or use of its affiliates, faculty, or employees names must have written approval of The Johns Hopkins University.

(b) All ingredient and finished Product labels, sales materials, promotional and advertising materials shall contain the following:

(i) Product produced under US Patents 5,725,895, 5,968,505, 5,968,567, 6,177,122, 6,242,018, 6,521,818 and other US [and international patents] licensed from Brassica Protection Products LLC.

(ii) SGS is a trademark of Brassica Protection Products LLC.

(c) SOPs shall describe in detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed. Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of the product.

9. Expiration Dating:

(a) To assure that the product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing.

(b) Expiration dates shall be related to the product when stored according to storage directions in the factory sealed container and confirmed by stability studies.

(c) The product shall contain not less than 100% of its stated strength or potency at date of release and date of expiration. Release and Expiration dates shall appear on all containers of product and Certificates of Analysis.

10. Storage and Distribution:

(a) Written procedures describing the warehousing of products shall be established and followed. They shall include:

(i) Quarantine of products before release by the quality control unit.

(ii) Storage of products under appropriate conditions of temperature, humidity, sanitation, and light so that the identity, strength, quality, and purity of the products are not compromised.

(b) Written procedures shall be established, and followed, describing the distribution of products. A return system and a separate "Recall" system shall be included in the SOPs for use in the event that material returns from a sale for reasonable or extreme reasons.

Material specifications:
SGS brand glucosinolate

Product Code:

Latin Binomial: *Brassica oleracea italica*
Production location(s): _____

Lot Number: ######
Date of Manufacture: Month DD, 200Y
Date of Expiry: Month DD, 200Y

Date:	
Customer No:	
Customer PO:	
Delivery No:	
Shipped Via:	
Vehicle/Vessel:	
Country of Origin:	
Special Requests:	
COA Prepared for:	

Test	Results	Limits	Methods
Glucoraphanin	%	NLT 5 %	HPLC – C18
Other Glucosinolates	%	NMT 1 %	HPLC – C18
pH		5 – 6	
Moisture	%	NMT 7 %, as is	AOAC/Karl Fisher
Heavy Metals, as Pb	ppm	LT 10 ppm	FCC
Lead (Pb)	ppm	LT 1.5 ppm	ICPMS
Arsenic (As)	ppm	LT 2.0 ppm	
Total Plate Count	/ g	NMT 3,000 per g	FDA – BAM
yeast & mold	/ g	NMT 100 per g	FDA – BAM 18
coliforms	per 25 g	Negative, per 25 g	FDA – BAM 4
e. coli	per 25 g	Negative, per 25 g	AOAC 2000.14
salmonella	per 25 g	Negative, per 25 g	AOAC 998.09

_____
Laboratory Manager

_____
Date of Issue

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